

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

**JOLANDI NICOLE KENNEDY AND,  
MARVIN LEVY, INDIVIDUALLY AND  
AS REPRESENTATIVES OF THE  
ESTATE OF MEAGHAN LEVY,**

**Plaintiffs,**

**V.**

**OXYSURE SYSTEMS, INC., JULIAN  
ROSS, et al.**

## Defendants.

[illegible]

**CAUSE NO. 3:16-cv-00065-B**

## RESPONSE IN OPPOSITION TO MOTION TO REMAND

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**I.**

**INTRODUCTION**

Defendant Oxysure Systems, Inc. (“Defendant”) files this *Response in Opposition to Motion to Remand*. The basis for this Court’s subject matter jurisdiction is federal preemption and the existence of a substantial federal question raised by Plaintiffs’ Petition that implicate the Food Drug and Cosmetic Act (FDCA) and its Medical Device Amendments (MDA), 21 U.S.C. § 301 et seq., and accompanying regulations. In short, a substantial federal question exists not because there is complete field preemption, but because this particular device, the Oxysure 615 Unit, is subject to a litany of FDA regulations for compliance, as well as post-market surveillance that certain claims raise the spectre of noncompliance, and their construction is necessary to ensure that Plaintiffs are not seeking to impose any requirements that are different from those of the FDA.

**II.**

**FACTUAL BACKGROUND & HISTORY**

**Meaghan Levy Chokes at School and  
Receives Oxygen from the Oxysure Unit**

There is little dispute about the preamble facts of this case. On December 12, 2013, at around 9:30 a.m. at Corbell Elementary School in Frisco, Meaghan Levy approached her teacher with her hands around her neck and in her mouth making a motion like she was choking.<sup>1</sup> The teacher tried to escort her to the Nurse’s office which was close by, but Meaghan collapsed, turned purple, and remained unresponsive.<sup>2</sup>

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<sup>1</sup> See *Kennedy et al. v. Oxysure Sys., Inc.*, CAUSE NO. 296-04298-2015, Original Petition at “Factual Background.” (“Kennedy Petition”). This court may take judicial notice of the allegations raised by Ms. Kennedy and Mr. Levy.

<sup>2</sup> See Exhibit A, Frisco ISD Investigative Notes; Exhibit B, Medical Examiner’s documents; and Exhibit E, Frisco Police Dep’t Investigation.

Parent volunteers at the school tried to do the Heimlich maneuver on Meaghan, but nothing came out of her mouth.<sup>3</sup> One of them attempted chest compressions, which caused “a large amount of foamy blood” to emanate from her mouth.<sup>4</sup>

After attempting CPR, the school nurse sought to administer oxygen using an Oxysure 615 Unit made by Defendant Oxysure Systems, Inc.<sup>5</sup> According to FRISCO ISD’s internal investigation documents obtained by Oxysure pursuant to an open records request, the nurse turned the Oxysure unit on for a few seconds and did not think it was working; so she unplugged the mask having never even put the mask on Meaghan (the “First Oxysure Unit”).<sup>6</sup>

Having disconnected the oxygen mask from the First Oxysure Unit, the nurse grabbed a second Oxysure unit (the “Second Oxysure Unit”), connected the mask to it and turned on the unit, and administered oxygen to Meaghan until the paramedics arrived.<sup>7</sup> Meanwhile, the First Oxysure Unit was indeed working and producing oxygen. The Frisco ISD investigator noted that it was “warm to the touch.”<sup>8</sup> But without the mask, oxygen built up inside it and caused a small rupture in the bottom of the canister, at which point a warm, thick wet slurry spilled out.<sup>9</sup>

The Frisco ISD investigation notes indeed show that the First Oxysure Unit had “no mask attached” and that there was “liquid leaking clear drying white.”<sup>10</sup> Meanwhile, those same notes

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<sup>3</sup> *Id.*

<sup>4</sup> *See* Exhibit B, Medical Examiner Documents, at pp. 5 of backup documents.

<sup>5</sup> *Id.*; Exhibit A, FRISCO ISD Investigative Notes.

<sup>6</sup> *See* Exhibit A, FRISCO ISD Investigative Notes.

<sup>7</sup> *See id.* The notes also reflect that the nurse reported she “turned on 1<sup>st</sup> not working. Unplugged mask, then started leaking. Put on Second Unit. Paramedics arrived.”

<sup>8</sup> *Id.*

<sup>9</sup> *See id.*

<sup>10</sup> *See id.*

reported about the Second Oxysure Unit, that: “Oxysure with mask. Mask attached with no Residue on mask nor cartridge.”<sup>11</sup>

The pictures accompanying the notes depict the two Oxysure units—one that is standing by itself with no mask attached and leaking a dark white substance on to the floor, and a second that is clear of any residue, with the Oxygen mask attached whose clear tubing is likewise free of any evidence of residue.<sup>12</sup>

An email from Frisco ISD’s investigator and compliance specialist, Russell Cunningham, to FISD’s risk manager, Tim Sanz, states that:

On December 13, 2013, I Russell Cunningham responded to a reported Oxysure malfunction at Corbell Elementary. Upon arrival I noticed there were two separate Oxysure Cartridges on the floor with one of them leaking and the other with the mask still attached. After taking some notes from the principal and the nurse over the phone, I contacted Danica Dixon which is a rep and the chemist for Oxysure. Danica determined that the first unit was activated but the mask removed prematurely causing the cartridge to crack and leak, then the same mask was used on the second unit which dispersed into the air normally because the paramedics were on the scene.<sup>13</sup>

The worst came true, and Meaghan Levy died an hour and a half later at Children’s hospital, having never regained consciousness and suffering through two cardiac arrests.<sup>14</sup>

**The Collin County Medical Examiner Concludes That  
Meaghan Levy Died of Asphyxiation Due to Choking on a Push-Pin**

The cause of death was determined by Dr. William Rohr, the Collin County Medical Examiner.<sup>15</sup> William Rohr, M.D. has served as the Collin County Medical Examiner for over thirty

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<sup>11</sup> *See id.*

<sup>12</sup> *See id.*

<sup>13</sup> *See id.* (Email from Russell Cunningham to Tim Sanz).

<sup>14</sup> *See* Exhibit B, Report and File of Collin County Medical Examiner.

<sup>15</sup> This section is taken entirely from the pages of Exhibit B, Report and File of Collin County Medical Examiner.

years, prior to which he served as the Chief Medical Examiner of the Iowa State Medical Examiner's office (appointed by the Governor), with an impeccable service record and professional designations.

According to Dr. Rohr's investigation, Meaghan Levy was taken to Children's Medical Center of Plano from Corbell Elementary. There she was x-rayed and it was discovered that she had been choking on a push-pin and possibly some food at the same time.<sup>16</sup> An autopsy was performed and concluded, as to her lungs and respiratory system:

The right lung is 500 grams and the left lung is 420 grams. Lungs are congested, edematous and airless. Distal airways are clear and contain no blood. There is no pulmonary thrombembolism. **Cut surfaces have reddish-purple parenchyma.** There is no evidence of consolidation. All lung lobes are examined microscopically. **There is early pneumonia, hyaline membrane formation, and underinflated alveoli.** Airways are unremarkable and without significant eosinophilic infiltrate. **There is aspiration of blood into parenchyma.**<sup>17</sup>

The Collin County Medical Examiner took several vials of blood and ran a broad post-mortem blood panel and toxicology screen. He concluded that:

**FINDINGS:**

1. History of apparent choking episode followed by unresponsiveness.
2. Push pin found within the stomach lumen.
3. Diffuse alveolar damage of lungs.

**CONCLUSION:** I am of the opinion that Meaghan Raynia Levy, a 5 year-old female, died as a result of asphyxia resulting from obstruction of her airway by a push-pin.<sup>18</sup>

Dr. Rohr's file and backup investigatory documents further reveal several facts:

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<sup>16</sup> The Autopsy notes that there was food lodged on part of the push pin.

<sup>17</sup> See *id.* at Autopsy Report, p. 2 (emphasis added).

<sup>18</sup> See *id.* at p. 3.

- Meaghan Levy had “seizure like activity” prior to the Oxysure unit being deployed and which continued through her arrival at Children’s Medical at Legacy Dr. in Plano.
- After the Heimlich maneuver was attempted, and before even attempting to administer oxygen, the nurse began chest compressions which caused “a large amount of foamy blood was seen emanating from the mouth and nose.”
- The doctors at the hospital “orally suctioned” Meaghan’s lungs and stomach and that “a lot of blood was present” and removed from her lungs.
- Dr. Rohr noted the above, and logically found that due to “blood in the lungs” she had possibly “aspirat[ed]” blood.
- “Blood work was done at the hospital” but revealed no toxicity.
- The nurse told the medical examiner that “when the decedent arrived to her she was already purple and was struggling to breathe.”<sup>19</sup>

These findings are notable for what they did not find: There is no mention in the Autopsy or in the accompanying medical file of any evidence of the alleged Oxysure powder or the salty slurry that Plaintiff alleges Meaghan ingested or breathed in. Moreover, a post-mortem toxicology screen was done on the blood, urine, and tissues and found no evidence of foreign chemicals or unexplained chemical agents.<sup>20</sup> The autopsy report lists no findings, and raises no potential questions arising from the toxicology report.<sup>21</sup> The Medical Examiner’s file shows that all samples that were taken from Meaghan Levy were sent to lab.<sup>22</sup> Moreover, her body was sent for cremation rather than burial.

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<sup>19</sup> See Medical Examiner’s File, generally.

<sup>20</sup> *Id.* The toxicology report is on page 23-36 of the file.

<sup>21</sup> See *id.* at Autopsy Report.

<sup>22</sup> See Exhibit B, generally.

### **Symone Redwine Puts Oxysure Through the Ringer**

The Kennedy Petition was filed on or about October 19, 2015, alleging that Meaghan Levy died as a result of exposure to poisons in the Oxysure Unit. Symone Redwine represented the plaintiffs in the lawsuit.<sup>23</sup> Plaintiffs and their counsel underwent a complete scorched Earth campaign to defame and injure Oxysure prior to filing this lawsuit.

Ms. Redwine sent Oxysure and counsel an email threatening Oxysure with ruinous publicity and harm to its business and reputation and market for its stock if Oxysure did not pay her and her clients.<sup>24</sup> Ms. Redwine faked a poisoning event and called Chemtrec, the poison control hotline to seek information about whether other people had been poisoned—none had been.<sup>25</sup> Ms. Redwine filed false reports with the FDA, sparking a highly expensive investigation and query from the FDA into Oxysure's products.<sup>26</sup> Ms. Redwine called Oxysure's insurance companies to make a claim on behalf of the family (despite not being an insured and without notifying Oxysure, the primary insured).<sup>27</sup> Ms. Redwine called and made accusations to Oxysure's suppliers, vendors, distributors and customers, to solicit information about injuries caused by the chemicals.<sup>28</sup> Ms.

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<sup>23</sup> Symone Redwine and the Redwine Law Firm is at least the fifth law firm to look at this case. The Medical Examiner's report reflects two law firms—Herman, Herman & Katz, in New Orleans, and Faith Johnson & Associates, LLP in Irving, Texas—requested the autopsy report and medical examiner's file. Neither of them even contacted Oxysure; apparently having turned the case down flat once they read the Medical Examiner's report. Two other lawyers likewise took the matter up on a different theory than the one sued under here, but did not file suit after speaking to the undersigned counsel about the lack of evidence. Only Ms. Redwine seems to have been immune to the lack of evidence supporting her theory.

<sup>24</sup> See Exhibit C, Email from Symone Redwine.

<sup>25</sup> See Exhibit D, Email thread with Chemtrec and Oxysure.

<sup>26</sup> See Affidavit of Mazin A. Sbaiti, Esq., December 17, 2015.

<sup>27</sup> See *id.*

<sup>28</sup> See *id.*

Redwine repeatedly contacted the Collin County Medical Examiner's office to attempt to convince them to change their finding on cause of death and find that the cause of death was poisoning.<sup>29</sup>

**Defendants Claim Levy Died of "Poisoning" As Opposed to "Asphyxiation"  
And the WFAA Defendants Broadcast the Lie Far and Wide**

Finding no evidence of poisoning, Ms. Redwine and her clients nonetheless made good on their threats against Oxysure. Simultaneously, they filed their lawsuit and contacted WFAA Television Channel 8, and its reporter, Mr. Jobin Panicker (with WFAA's parent, Tegna Inc., "WFAA" or the "WFAA Defendants") proclaiming their unhinged "caustic chemical poisoning" theory as established fact.<sup>30</sup>

WFAA was all too willing to oblige, airing the story on Wednesday, October 21, 2015, before Oxysure was even served with the petition. The story's focus was that Meaghan Levy did not die of asphyxiation like the Medical Examiner claimed; she died of "caustic chemical poisoning" from inhaling the dry salts or aspirating the slurry in the First Oxysure Unit.

Some of the more salacious statements were that:

- The pushpin could not have caused Meaghan Levy's death ... "It just didn't... the details didn't add up,' Kennedy said," the Story says.
- Selectively citing "a police report obtained by WFAA" for two snippets: "the oxygen bottle malfunctioned" and mischaracterizing that "[e]ven the nurse trying to help was taken to the hospital after being 'exposed to chemicals inside'."
- That the putative "failure...put lethal chemicals into the kindergarten student."
- "'What *they're* actually dying of is called chemical asphyxiation.'" (emphasis added).

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<sup>29</sup> See Affidavit of Mazin A. Sbaiti, Esq., December 17, 2015.

<sup>30</sup> The link to the story is here: <http://www.wfaa.com/story/news/local/collin-county/2015/11/03/family-links-girls-death-oxygen-device/74312940/>. A year ago, WFAA covered the story, but back then they were blaming it on the push-pin and espousing a theory of negligence on the part of the school district. <http://www.wfaa.com/story/news/local/collin-county/2014/08/21/14219288/>

- That Meaghan Levy and others died of “caustic chemical poisoning.”
- “What they’re dying from [is] caustic chemical poisoning.”
- That the “oxygen generating agent in the Oxysure device contains sodium carbonate.”
- “The cartridge in that same device was voluntarily recalled by the company in July,
- “Three months earlier, in September 2013, an Oxysure cartridge had ‘ruptured,’ according to the police report. That incident sent six people to the hospital at Lone Star High School.”
- The picture of the ruptured canister was from Lonestar high school, not the one from Corbell Elementary.

Among others. The Video was provided with WFAA’s Anti-SLAPP motion.

The story set off a radical drop in Oxysure’s stock price. Shares had been cyclical prior to that, but right after the story, Oxysure’s shares dropped from \$0.25 per share to \$0.21 per share, and went down to \$0.17 per share by November 11, 2015 – which was only temporarily staunched only by Oxysure’s release of its third quarter earnings. The \$0.04 per share loss equaled \$1.44 million. Four other school districts *immediately* cancelled their pending orders, which was revealed to have been based upon the News story and the follow-up chatter about the poisoning incident, costing Oxysure another estimated \$1.4 million.

### **Redwine and Meaghan Levy’s Parents Run Away From the Lawsuit at the First Challenge**

Knowing that the Levy parties lacked evidence of injury (counsel had requested what evidence Ms. Redwine had on multiple occasions and she produced nothing). Oxysure filed a no-evidence motion for summary judgment solely on the issue of Meaghan’s alleged poisoning (as

opposed to asphyxiation).<sup>31</sup> Oxysure therein noted that it had zero evidence that would bear upon the answer to that threshold question—other than what it had obtained from the Medical Examiner, Frisco ISD, and Frisco P.D., which Miss Kennedy and Mr. Levy already had or should have had. Oxysure also moved for a Level III Scheduling Order that limited initial discovery to the threshold issue of whether Meaghan died of poisoning instead of from asphyxiation caused by the pushpin.<sup>32</sup>

Miss Kennedy and Mr. Levy had two years to adduce evidence of the injury—which would be completely in their custody and control if it exists at all. Rather than come forward with evidence in response to Defendant’s discovery requests, or with the necessary evidence to respond to the motion for summary judgment, Plaintiffs instead filed a motion to non-suit, and two days later refiled the case in Dallas County, adding twenty new defendants, but sticking to the same set of meritless facts and legal theories.<sup>33</sup>

On February 15, 2016, Judge Roach of the 296<sup>th</sup> District Court granted Oxysure \$35,000 in sanctions it had requested against Jolandi Nicole Kennedy, Marvin Levy, Symone Redwine, and The Redwine Law Firm for filing a frivolous lawsuit, forum shopping, among other things.

### III.

#### THE LAW

Removal is permitted by a defendant where there is a substantial federal question implicated, even if the well-pleaded complaint does not raise a federal claim. *See, e.g., Torres v. Southern Peru Copper Corp.*, 113 F.3d 540, 542-43 (5th Cir. 1997); *accord* Republic of

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<sup>31</sup> *See Kennedy et al. v. Oxysure Sys. Inc.*, Case No. 296-04298-2015 (296<sup>th</sup> Dist. Ct., Collin County), Defendant’s Motion for No Evidence Summary Judgment, filed November 6, 2015, at p. 6; *see also* Affidavit of Julian in Support of Motion for Summary Judgment, sworn to November 6, 2015, at ¶ 4.

<sup>32</sup> *See id.* Defendant’s Motion for Amended Level III Scheduling Order, filed November 6, 2015.

<sup>33</sup> *See Kennedy et al v. Oxysure Sys. Inc. et al.*, Cause No. DC-15-14807 is before the 162<sup>nd</sup> District Court in Dallas County. Plaintiffs must apparently think they have a better shot at manipulating the judicial process there. It is hard to tell which court ought to be more insulted.

*Philippines v. Marcos*, 806 F.2d 344, 352 (2d Cir. 1986); *Sequihua v. Texaco, Inc.*, 847 F. Supp. 61, 62-63 (S.D. Tex. 1994). The substantial federal question exception to the well-pleaded complaint rule arises “where the vindication of a right under state law necessarily turn[s] on some construction of federal law.” *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 9 (1983). *see also Landers v. Morgan Asset Mgmt. Inc.*, No. 08-2260, 2009 U.S. Dist. LEXIS 30891, 2009 WL 962689, \*5 (W.D. Tenn. Mar. 31, 2009) (“Where a well-pleaded complaint does not seek relief under federal law, a court may find removal proper if the plaintiff’s complaint raises a ‘substantial’ federal question.”).

The Supreme Court has identified four aspects of a case or an issue that affect the substantiality of the federal interest in that case or issue:

(1) whether the case includes a federal agency, and particularly, whether that agency’s compliance with the federal statute is in dispute;

(2) whether the federal question is important (i.e., not trivial);

(3) whether a decision on the federal question will resolve the case (i.e., the federal question is not merely incidental to the outcome); or

(4) whether a decision as to the federal question will control numerous other cases (i.e., the issue is not anomalous or isolated). *See Mikulski*, 501 F.3d at 570. *See also Medical Device Acts of 1976*, § 360k(a).<sup>34</sup>

#### IV.

#### DISCUSSION

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<sup>34</sup> 21 U.S.C. § 360K(a) provides: “**General rule:** Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”

Plaintiffs fail to discuss any of the salient issues in their opening brief—focusing exclusively on the lack of field preemption for the Oxysure Unit. Their motion to Remand is bereft of any applicable law, facts, or allegations that would require remand to state court.<sup>35</sup> We address the basic contention for removal here:

While the Oxysure 615 Unit is a Class II device, it is governed by a series of FDA regulations and guidelines that Oxysure must comply with. This is more so than the average Class II device which only is governed by “substantial equivalence.”<sup>36</sup> Thus, removal is proper because certain of Plaintiffs’ claims require the Court to impose requirements on Oxysure that are different or in conflict with those imposed by the FDA, *accord* 21 U.S.C. § 360K(a), which determination requires construction of the FDA’s regulations and guidance.

For example, the FDA regulations require a sustained flow-rate of 6 litres per minute of pure medical grade oxygen for fifteen minutes.<sup>37</sup> Oxysure’s research identified only two chemicals that when combined with activators and water, produced the required flow rate.<sup>38</sup> However the petition suggests that the chemicals are “caustic” and inherently dangerous, and suggests that the combination or chemical reaction was a design defect ... i.e., that there is a safer design or chemical combination – irrespective of the flow rate.<sup>39</sup> As part of their claims for design defect, under Texas law (whether under Tex. Civ. Prac. Rem. Code § 82.005 or at common law), Plaintiffs will have to prove the utility of the use of the chemicals was outweighed by the risks (whatever those are), which necessarily implicates the applicability and construction of the FDA regulations as applied

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<sup>35</sup> To the extent they intend to sandbag Oxysure, Oxysure reserves its right to seek a sur-reply when Plaintiffs indeed decide to address the merits and the facts.

<sup>36</sup> See Decl. of Julian Ross.

<sup>37</sup> See Exhibits A and B to Decl. of Julian Ross.

<sup>38</sup> See Decl. of Julian Ross.

<sup>39</sup> See Decl. of Julian Ross.

to Oxysure because they approved such devices as necessary to obviate the risks to those in need of medical oxygen.<sup>40</sup>

Furthermore, the complaint suggests that the design of the Oxysure Unit was defective or negligent because it allowed the chemicals to get into the oxygen mask that Meaghan Levy was breathing from. The degree of filtration of any dust particles directly implicates the accessibility and purity of the Oxygen which is likewise subject to FDA regulations for emergency medical grade oxygen.<sup>41</sup> In other words, whether more filtration was feasible and if so, whether compliance with the FDA's requirement was feasible with that addition.<sup>42</sup>

Additionally, the complaint attacks Oxysure's manufacturing claiming a defect – e.g., attacking Oxysure's compliance with the FDA required Good Manufacturing Practices. The vague attack raises the question of the sufficiency and propriety of Oxysure's compliance with those GMP's which are FDA required.<sup>43</sup>

In essence, all of the design and manufacturing defect claims implicate Oxysure's compliance with the FDA's regulations, and require a construction and application to test the thesis of the Plaintiffs in these particular claims. This is not a trivial question – it is central, and its resolution in Oxysure's favor will dispense with a great majority of the claims herein. The balance of Plaintiffs claims fall under this Court supplemental jurisdiction, 28 U.S.C. § 1367.

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<sup>40</sup> *Id.*

<sup>41</sup> *See* Exhibits A and B; *see also* Julian Ross Decl.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

Respectfully submitted this 11<sup>th</sup> day of March, 2016.

**STECKLER LLP**

/s/ Mazin A. Sbaiti

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**CERTIFICATE OF SERVICE**

This is to certify that on the 11<sup>th</sup> day of March, 2016, a true and correct copy of the above and foregoing instrument was served via E-Filing and/or First Class mail, upon the following counsel of record in accordance with the Federal Rules of Civil Procedure:

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And upon all Defendants listed in the Original Petition.

/s/ Mazin A. Sbaiti

Mazin A. Sbaiti, Esq.